

**REMARKS**

Claims 42-100 are pending and claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76 and 78-81 currently under examination. Claims 43, 47, 48, 50, 55-67, 70, 74, 75, 77 and 82-100 stand withdrawn from consideration as drawn to unelected species or a restricted invention. In the present paper, claims 42, 68, and 70-93 are amended and claims 69 and 94-100 are cancelled without prejudice to Applicants' right to pursue the cancelled subject matter in one or more related applications. Applicants respectfully request reconsideration of the pending claims in light of the amendments and remarks presented herein.

Applicants note that claims 43, 47, 48, 50, 55-67, 70, 74, 75, 77 and 82-93 relate to non-elected species, and that claims 42 and 68 are generic to such claims. As such, Applicants believe that claims 43, 47, 48, 50, 55-67, 70, 74, 75, 77 and 82-93 should be examined following determination of the patentability of claims 42 and 68. Applicants respectfully request such examination and an indication of the allowability of such claims following an allowance of claims 42 and 68.

**I. The Amendments to the Claims**

In the present paper, claims 42, 68, and 70-93 are amended and claims 69 and 94-100 are cancelled. The amendments to the claims are fully supported by the application as filed. In particular, specific support for the amendments to claims 42 and 68 may be found, for example, in claim 1 as filed. Claims 70-93 have been amended to correct their dependencies. Thus, no new matter is presented by the amendments to the claims. Entry thereof is therefore respectfully requested under 37 C.F.R. § 1.111.

**I. The Anticipation Rejection**

Claims 42, 45, 46, 49, 51, 52, 68, 69, 72, 73, 76, 78, and 79 stand rejected as allegedly anticipated by Rodlebo *et al.*, 1999, *Am J. Physiol. Lung Mol. Physiol.* 276:229-238. Without acquiescing to the propriety of the rejection, claim 42 has been amended to recite that subject as been exposed to cigarette smoke. Accordingly, Applicants believe the rejection is moot with respect to claim 42 and the claims depending therefrom.

With respect to claim 68, Applicants respectfully submit that claim 68 recites a method for treating damage caused by cigarette smoke...in a subject in need thereof.

Accordingly, Applicants believe that the subjects recited in claim 68 have been previously exposed to cigarette smoke. The Examiner appears to indicate that the subject population of Rodlebo *et al.* is one that has not had contact with cigarette smoke, a different subject population from that of claim 68. *See* Office Action, page 3. As such, Rodlebo *et al.* fails to disclose each and every element of the invention as claimed, and therefore cannot anticipate claim 68. *See In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir., 1990). Accordingly, Applicants respectfully request withdrawal of the rejection of claim 68, and the claims depending therefrom.

### **III. The Indefiniteness Rejection**

Claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76, and 78-81 stand rejected as allegedly indefinite under 35 U.S.C. § 112, second paragraph. In particular, the Examiner argues that the claims recite a substance P analog that is of indeterminate structure, causing the claims to be indefinite in scope.

Claim 42 and claim 68 as currently amended each recite a limitation defining the structure of the substance P analogs used in the claimed methods. Thus, the analogs recited by the claims are not of indeterminate structure, but in fact are selected from the group consisting of [Met-OH<sup>11</sup>]-substance P, [Met-OMe<sup>11</sup>]-substance P, [Nle<sup>11</sup>]-substance P, [Pro<sup>9</sup>]-substance P, [Sar<sup>9</sup>]-substance P, [Tyr<sup>8</sup>]-substance P, [p-Cl-Phe<sup>7,8</sup>]-substance P, and [Sar<sup>9</sup>, Met(O<sub>2</sub>)<sup>11</sup>]-substance P. As such, Applicants believe the rejection of claim 42, and the claims depending therefrom, is in error and the rejection of claim 68, and the claims depending therefrom, are moot in view of the amendments to the claims. Applicants therefore respectfully request withdrawal of the rejection of claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76, and 78-81 under 35 U.S.C. § 112, second paragraph.

### **IV. The Written Description Rejection**

Claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76, and 78-81 stand rejected as lacking written description under 35 U.S.C. § 112, first paragraph. In particular, the Examiner argues that the claims recite a substance P analog that is of indeterminate structure, causing the claims to be lack description in the application as filed.

As discussed above, Applicants respectfully submit that the substance P analogs recited by the claims are limited to those selected from the group consisting of [Met-OH<sup>11</sup>]-

substance P, [Met-OMe<sup>11</sup>]-substance P, [Nle<sup>11</sup>]-substance P, [Pro<sup>9</sup>]-substance P, [Sar<sup>9</sup>]-substance P, [Tyr<sup>8</sup>]-substance P, [p-Cl-Phe<sup>7,8</sup>]-substance P, and [Sar<sup>9</sup>, Met (O<sub>2</sub>)<sup>11</sup>]-substance P. As such, Applicants believe the rejection of claim 42, and the claims depending therefrom, is in error and the rejection of claim 68, and the claims depending therefrom, are moot in view of the amendments to the claims. Applicants therefore respectfully request withdrawal of the rejection of claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76, and 78-81 under 35 U.S.C. § 112, first paragraph.

#### **IV. The Enablement Rejection**

Claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76, and 78-81 stand rejected as not enabled under 35 U.S.C. § 112, first paragraph. In particular, the Examiner argues that the specification fails to enable a method for preventing damage caused by cigarette smoke.

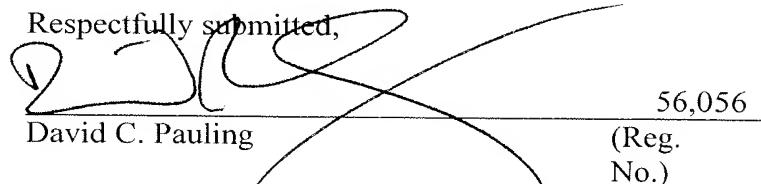
Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, claim 42 has been amended to recite a method for ameliorating damage caused by cigarette smoke. As such, Applicants believe the rejection of claim 42, and the claims depending therefrom, is moot in view of the amendments to the claims.

With respect to claim 68, Applicants note that claim 68 recites a method for treating damage caused by cigarette smoke, which the Examiner agrees is enabled by the application as filed. *See* Office Action, page 9. Accordingly, Applicants believe the rejection is in error with respect to claim 68, and the claims depending therefrom. Applicants therefore respectfully request withdrawal of the rejection of claims 42, 44-46, 49, 51-54, 68, 69, 71-73, 76, and 78-81 under 35 U.S.C. § 112, first paragraph.

**V. Conclusion**

A fee of \$555.00 is believed due for the three-month extension of time. If any additional fees are due for the submission of this paper or to avoid abandonment of this application, please charge them to Deposit Account No. 50-3013 (reference 876946-999022).

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Respectfully submitted,  
  
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